

## CLAIMS

We claim:

1. A breath simulator device for checking the system functionality of a breath test instrument, which provides gas samples to simulate exhaled breaths of a subject.
2. A breath simulator device according to claim 1 and wherein said simulation of exhaled breaths of a subject, comprises at least one of the properties selected from the group consisting of flow rate, total gas species concentration, isotopic ratio of said gas species sample, and respiration rate.
3. A calibration checking device comprising a porous tube which allows preferential diffusion through its wall of one component of a calibrating gas.
4. A calibration checking device according to claim 3 and wherein said porous tube is operative to amend the isotopic ratio of a calibrating gas during passage through it.
5. A calibration checking device according to claim 4 and also comprising gas switching means for alternating the output of said device between calibration gas with and without an amended isotopic ratio.
6. A calibration checking device according to claim 5 and wherein said gas switching means is also operative for alternating the output of said device between calibration gas with an amended isotopic ratio, calibration gas without an amended isotopic ratio, and air without any calibrating gas.

7. A system checking device according to claim 6 and wherein said gas switching means operates at a switching rate in a range similar to human respiration rate.
8. A calibration checking device comprising:
- a calibrating gas inlet conduit supplying calibrating gas to a porous tube, said porous tube allowing preferential diffusion through its wall of one component of said calibrating gas;
  - a calibrating gas outlet conduit, conveying calibrating gas with an amended composition from said porous tube; and
  - an outer chamber through which said porous tube passes, said outer chamber being continually flushed with a purging gas to remove any component of said calibrating gas which diffuses through said wall of said porous tube.
9. A calibration checking device according to claim 8 operative to amend the isotopic ratio of a calibrating gas during passage through it.
10. A calibration checking device according to claim 9 and also comprising gas switching means for alternating the output of said device between calibration gas with and without an amended isotopic ratio.
11. A calibration checking device according to claim 10 and wherein said gas switching means is also operative for alternating the output of said device between calibration gas with an amended isotopic ratio, calibration gas without an amended isotopic ratio, and air without any calibrating gas.
12. A calibration checking device according to claim 11 and wherein said gas switching means operates at a switching rate in a range similar to a human respiration rate.

13. A breath tester incorporating a calibration checking device according to claim 12, and also comprising a receiver into which is inserted a container of calibrating gas, said receiver including means for enabling a calibration checking procedure in said breath tester.
14. A breath tester according to claim 13, and wherein said container of calibrating gas is made of glass, and insertion of said container into said receiver actuates breakage of said glass, thereby releasing said calibrating gas.
15. A breath tester according to claim 13, and wherein said container of calibrating gas is closed by means of a pressure seated check valve, and insertion of said container into said receiver depresses said check valve, thereby releasing said calibrating gas.
16. A breath tester according to claim 13, and wherein said container of calibrating gas is closed by means of a thin metallic foil, and insertion of said container into said receiver enables a needle to penetrate said thin foil, thereby releasing said calibrating gas.
17. A breath tester according to claim 13, and wherein said container of calibrating gas is a hermetically sealed flexible plastic bag
18. A breath tester incorporating a calibration checking procedure, operative to ensure that said breath tester is enabled only if a routine mandatory calibration check is performed after a predetermined number of breath tests.
19. A breath tester according to claim 18, and also operative to ensure that said breath tester is enabled only if an authorized and new container of calibration gas is used for said routine mandatory calibration check.

20. A method of calibrating a breath tester comprising the steps of:
- performing a calibration check on said breath tester by the use of at least two gases having known isotopic ratio differences between them;
  - comparing the deviation in the differences in the isotopic ratios measured by said breath tester from those of said at least two gases; and
  - performing a calibration of said breath tester if said deviation exceeds a predetermined value.
21. A calibration checking device for use with a gas analyzer, comprising:
- a calibration checking unit; and
  - an enabling mechanism for enabling operation of said gas analyzer.
22. A calibration checking device for use with a gas analyzer according to claim 21 and wherein said enabling mechanism is operative to count the number of tests performed by said gas analyzer.
23. A calibration checking device for use with a gas analyzer according to claim 21 and wherein said enabling mechanism is operative to accumulate the time of operation of said gas analyzer.
24. A calibration checking device for use with a gas analyzer according to claim 21 and also comprising a filter for removing fluids from a gas to be analyzed.
25. A calibration checking device for use with a gas analyzer according to claim 21 and wherein said enabling mechanism is actuated by the use of said calibration checking unit.

26. A calibration checking device for use with a gas analyzer according to claim 24 and wherein said enabling mechanism for enabling operation of said gas analyzer is operated by said filter.
27. A calibration checking device for use with a gas analyzer according to claim 21 and wherein said enabling mechanism is communicative with said gas analyzer by means of a signal selected from a group consisting of electrical, electronic, optical, mechanical, magnetic, pneumatic and gaseous signals.
28. A calibration checking device for use with a gas analyzer according to claim 21 and wherein said enabling mechanism is operative to ensure proper location of said calibration checking unit.
29. A calibration checking device for use with a gas analyzer according to claim 21 and wherein said enabling mechanism comprises optical transmitter and receiver means, the optical path between which is completed by reflection from said calibration checking unit only when said calibration checking unit is properly located in said gas analyzer.
30. A calibration checking device for use with a gas analyzer, comprising:  
a calibration checking unit; and  
a count actuating mechanism initiated by first use of said calibration checking device, operative to begin a count of the number of tests performed with said calibration checking device.
31. A calibration checking device for use with a gas analyzer according to claim 30 and also comprising a filter for removing fluids from the gas to be analyzed.

32. A calibration checking device for use with a gas analyzer according to claim 30 and wherein said count actuating mechanism is actuated by said calibration checking unit.
33. A calibration checking device for use with a gas analyzer according to claim 31 and wherein said count actuating mechanism is actuated by said filter.
34. A calibration checking device for use with a gas analyzer according to claim 30 and wherein said count is used to prevent use of said gas analyzer after a predetermined number of tests have been performed.
35. A calibration checking device for use with a gas analyzer according to claim 30 and wherein said count of the number of tests performed with said calibration checking device is performed within the gas analyzer.
36. A calibration checking device for use with a gas analyzer according to claim 30 and wherein said count of the number of tests performed with said calibration checking device is performed within the calibration checking device.
37. A calibration checking device for use with a gas analyzer according to claim 30 and wherein said count actuating mechanism is communicative with said gas analyzer by means of a signal selected from a group including electrical, electronic, optical, mechanical, magnetic, pneumatic and gaseous signals.
38. A calibration checking device for use with a gas analyzer according to claim 21 and wherein said calibration checking unit releases a calibration checking gas of known composition into said gas analyzer.

39. A calibration checking device for use with a gas analyzer according to claim 38 and wherein said enabling mechanism is actuated by release of said calibration checking gas.
40. A calibration checking device for use with a gas analyzer according to claim 30 and wherein said calibration checking unit releases a calibration checking gas of known composition into said gas analyzer.
41. A calibration checking device for use with a gas analyzer according to claim 40 and wherein said count actuating mechanism is actuated by release of said calibration gas.
42. A calibration checking device for use with a gas analyzer according to claim 21 and wherein said enabling mechanism is actuated by means of an active integrated circuit disposed on said calibration checking device
43. A calibration checking device for use with a gas analyzer according to claim 30 and wherein said count actuating mechanism is actuated by means of an active integrated circuit disposed on said calibration checking device
44. A calibration checking device for use with a gas analyzer according to claim 30, and also comprising a disabling device which prevents said count actuating mechanism from being reinitiated after first use of said calibration checking device.
45. A calibration checking device for use with a gas analyzer according to claim 24 and wherein said filter is a section of a sampling tube having built-in fluid filtering properties.

46. A calibration checking device for use with a gas analyzer according to claim 42 and also comprising a filter for removing fluids from a gas to be analyzed.

47. A calibration checking device for use with a gas analyzer according to claim 46 and wherein said filter comprises a drying agent disposed in proximity to at least part of an inside wall of said sampling tube.

48. A calibration checking device for use with a gas analyzer according to claim 24 and wherein the construction of said calibration checking unit and said filter are such as to essentially maintain the waveform of a breath of gas to be analyzed.

49. A calibration checking device for use with a gas analyzer, comprising:

- a sampling line for conveying a gas to be analyzed to said gas analyzer;
- at least one enclosure housing at least one container of calibration gas;
- at least one mechanism for releasing said calibration gas in said at least one container into said enclosure, said mechanism having interactive control contact with said gas analyzer; and
- at least one delivery conduit connecting between said enclosure and said sampling tube for conveying said calibration gas after release into said sampling line.

50. A calibration checking device for use with a gas analyzer according to claim 49 and wherein said interactive control contact comprises the actuation of said mechanism by means of said gas analyzer



51. A calibration checking device for use with a gas analyzer according to claim 49 and wherein said interactive control contact comprises the transmission of a signal to said gas analyzer on actuation of said mechanism.
52. A calibration checking device for use with a gas analyzer according to claim 49, and wherein said at least one container of calibration gas comprises two containers of calibration gas.
53. A calibration checking device for use with a gas analyzer according to claim 49, and wherein said at least one delivery conduit comprises two delivery conduits.
54. A calibration checking unit for use with a gas analyzer, comprising:  
a calibration gas mixture comprising at least a first and a second gas; and  
a delivery conduit for conveying said calibration gas mixture to said gas analyzer, said delivery conduit comprising a material which allows preferential diffusion through its wall of at least one of said at least a first and a second gas.
55. A calibration checking unit for use with a gas analyzer according to claim 54, and wherein said material is a selective membrane.
56. A calibration checking unit for use with a gas analyzer according to claim 54, and wherein said material is a porous diffusive tube.
57. A kit for calibration checking a gas analyzer comprising at least one calibration checking unit and a plurality of disposable sampling tubes for each of at least one calibration checking unit.

58. A kit for calibration checking a gas analyzer according to claim 57, and wherein at least one of said sampling tubes comprises a fluid filter.
59. A kit for calibration checking a gas analyzer comprising:  
at least one calibration checking unit capable of interactive communication with said gas analyzer; and  
a plurality of disposable sampling tubes for each of said at least one calibration checking unit.
60. A kit for calibration checking a gas analyzer according to claim 59, and wherein at least one of said sampling tubes comprises a fluid filter.
61. A calibration checking unit operative to generate a second calibration material from a first material input thereto.
62. A calibration checking unit according to claim 61 and wherein said first material is also a calibrating material.
63. A calibration checking unit according to claim 61 and wherein said materials are gases for use in a gas analyzer.
64. A breath bringer which changes a characteristic during use.
65. A breath bringer according to claim 64, and wherein said characteristic is a color.
66. A calibration checking device for use with a gas analyzer according to claim 21 and wherein said enabling mechanism is operative to accumulate the time since the last calibration check of said gas analyzer.